

Disintegration

Background: Disintegration Testing

Before the active ingredient(s) of an oral solid dose drug product can be absorbed into the body, the tablet or capsule in which they are contained must first disintegrate into smaller particles.

Chapters Ph. Eur. 2.9.1 and USP <701> and <2040> describe reproducible and standardised methods for quantifying the disintegration behaviour of solid dosage forms.



Disintegration

Test Apparatus & Method

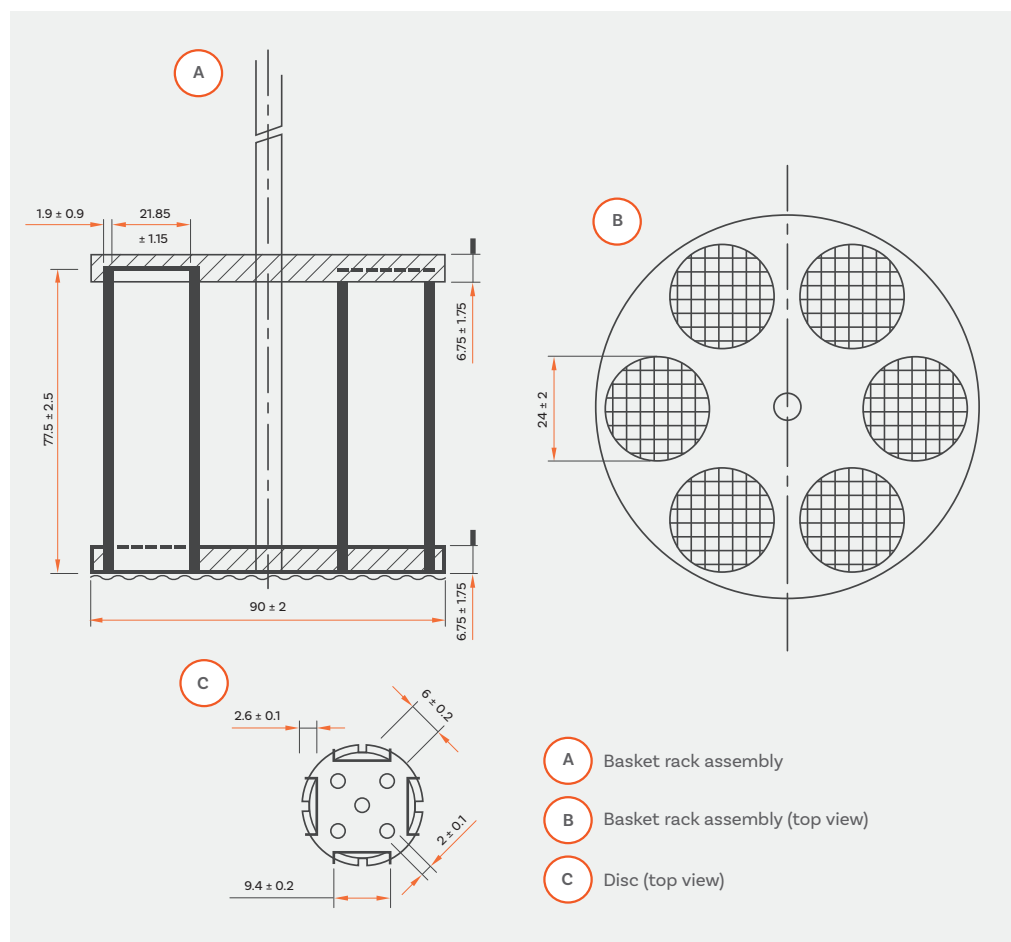
Typically, the tablets and capsules to be tested are each placed in one of six vertical tubes each measuring approx. 77.5 mm long x 21 mm inside diameter, positioned in a circular basket arrangement.

The lower end of each tube is covered by a 2 mm sieve mesh. Large tablets, capsules and boluses may require a larger basket.

The basket assembly is raised and lowered in simulated gastric fluid at body temperature (37 °C) through a distance of 55 mm, at a constant stroke frequency of 30 cycles per minute. A plastic disc of

precise geometry “hammers” the tablet during the operation, thus assisting in the disintegration process.

The tablet is said to pass the test providing that no tablet residue remains on the sieve mesh after the designated time, typically 30 minutes for ordinary tablets and 60 minutes for enteric-coated tablets.



Disintegration: DTGi Series

Reproducible, standardised and affordable disintegration testing

The result of decades of innovation and experience in the field of pharmaceutical testing, the Copley DTGi series of disintegration testers simplifies testing within R&D and QC environments. Suitable for a wide range of tablet and capsule types (e.g. plain-coated tablets, delayed-release, gelatine etc.), the DTGi tester series is an affordable range of disintegration testers, that complies fully with specifications defined in Ph. Eur., USP and associated Pharmacopoeias.

Controlled via our intuitive touchscreen interface, the Copley DTGi Series features 1, 2, 3 and 4 station units as well as a 2-station independent control unit, ideal for testing tablets and capsules under varying conditions. The user-friendly design makes assessing disintegration characteristics a simple touch-of-a-button task.



Ph. Eur. and USP compliant



Integrated, precision temperature control and measurement



Intuitive touchscreen control to simplify operation



Single-point electronic temperature calibration



One to four test station unit configurations, plus independent station control unit option



Extensive data reporting output options



Adjustable stroke frequency control for accelerated or high sensitivity testing



Option to automate and remotely control DTGi systems



DTGi Series: Key Features



Quick-release baskets for rapid sample loading, unloading and cleaning



Intuitive touchscreen control with icon-based menu structure simplifies operation and clearly displays test parameters throughout run



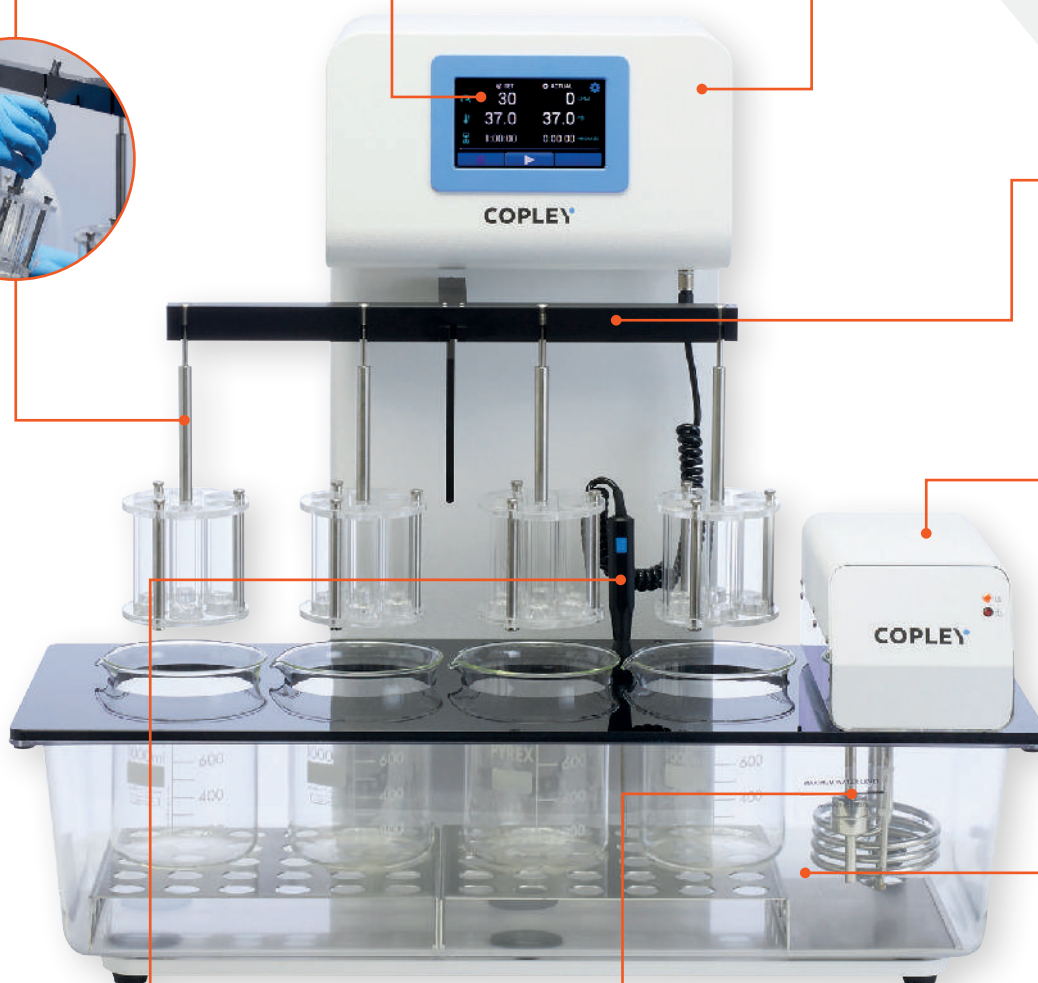
Robust metal case with advanced corrosion protective coating



Basket rack assemblies are automatically lowered and raised to/from test media at start and end of test



Independent digital heater/circulator maintains a constant temperature and minimises vibration



Easily removable leak-proof water bath with convenient drain tap eases bath water emptying



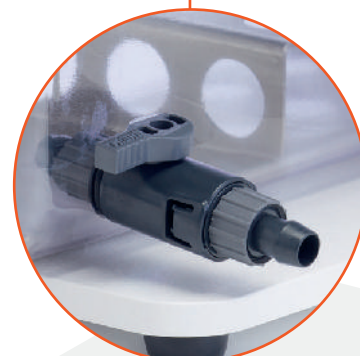
PT100 temperature probe monitors bath and media temperature



Maximum fill line indicator



Note: A low-working noise level is generated by the equipment ensuring a comfortable working environment



DTGi Series: Touchscreen User Interface



Key Features:

- **Intuitive menu structure** enables users to locate features quickly and easily
- **Easy-set** user-configurable **test parameters**:
 - Speed (cycles per minute)
 - Temperature (°C)
 - Report output settings menu
- Status of '**Actual**' v '**Set**' test **parameters clearly displayed** throughout testing
- **Test progress bar** provides clear and constant indication on run status
- Resistive touchscreen interface can be **operated with gloves on**
- Hygienic **wipe-clean** screen
- **Passcode-protected** temperature calibration
- High productivity - **easy system set-up and operation** minimises training burden.

- A** Setting a test parameter
- B** Set v Actual test parameters (before test run)
- C** Set v Actual test parameters (during test run, with test progress bar)
- D** Settings menu
- E** Passcode-protected temperature calibration process
- F** Temperature calibration
- G** Report output settings menu



Reporting

Extensive data output options are available as standard, including direct reporting to a printer or PC.

Reported parameters

- **Speed (cycles per minute)**

Set
Average
Maximum
Minimum



RS 232

- **Temperature (°C)**

Set
Average
Maximum
Minimum



USB A



USB B

- **Test Duration (HH:MM:SS)**

Set
Actual

- **Calibration Data**

Calibration date
Temperature calibrated at (°C)

Compliance & Maintenance



- ✓ Certificate of compliance to Ph. Eur./USP provided as standard
- ✓ Comprehensive IQ/OQ/PQ documentation packages and toolkits available
- ✓ Passcode-protected single-point electronic temperature calibration
- ✓ Latest temperature calibration information stored and available to export/print

Choose your DTGi Disintegration System



DTG 100i

Cat. Number
1231

No. Test Stations
1

Tablet Capacity
6

Independent Station Control
No

Unit Dimensions (w x d x h)
450 x 473 x 657 mm



DTG 200i

Cat. Number
1232

No. Test Stations
2

Tablet Capacity
12

Independent Station Control
No

Unit Dimensions (w x d x h)
450 x 473 x 657 mm



DTG 300i

Cat. Number
1233

No. Test Stations
3

Tablet Capacity
18

Independent Station Control
No

Unit Dimensions (w x d x h)
700 x 473 x 657 mm



DTG 400i

Cat. Number
1234

No. Test Stations
4

Tablet Capacity
24

Independent Station Control
No

Unit Dimensions (w x d x h)
700 x 473 x 657 mm



DTG 200i-IS

Cat. Number
1238

No. Test Stations
2

Tablet Capacity
12

Independent Station Control
Yes

Unit Dimensions (w x d x h)
515 x 473 x 657 mm

Independent Station Control: DTG 200i-IS

With the same standard features as the other DTGi systems, the DTG 200i-IS offers independent control over each test station, making it ideal for the following types of applications:

- Comparing one formulation directly against another
- Comparing the performance of a single formulation under different conditions
- Assessing delayed release or enteric coated tablets where samples must be immersed for specified periods of time in different media
- Allowing two users to run tests simultaneously

DTGi Series: Technical Specifications

| | |
|----------------------------------|-----------------------------------------------------------------------------------------|
| Pharmacopoeial Compliance | Ph. Eur. Chapter: 2.9.1 USP Chapter: <701> and <2040> |
| User Interface | Resistive touchscreen |
| Basket Rack Assembly | Automatically lowered and raised at beginning and end of test run |
| Stroke Frequency Range | 10 - 50 strokes/min |
| Stroke Height | 55 ± 1 mm |
| Heater Type | Independent digital heater/circulator |
| Heater Temperature Range | Ambient - 50 °C |
| Test Run Time | Up to 99 hours , 59 minutes, 59 seconds |
| Alarm(s) | 1. End of testing (audible) 2. Low bath water level warning on-screen indicator |
| Data Output | RS 232 USB A (for connection with a USB printer) USB B (for connection with a PC) |

Temperature Calibration



Single-point electronic temperature calibration.

Calibration of the DTGi Series temperature probe is simple, through the use of an electronic calibration key and passcode-protected calibration menu

designed to guide users through the process without fuss. The latest temperature probe calibration information is stored and available to print/export when convenient to the user.

DTGi Series

| Cat. No. | Description |
|----------|----------------------------------------------------|
| 1231 | Disintegration Tester Model DTG 100i |
| 1232 | Disintegration Tester Model DTG 200i |
| 1233 | Disintegration Tester Model DTG 300i |
| 1234 | Disintegration Tester Model DTG 400i |
| 1238 | Disintegration Tester Model DTG 200i-IS |
| 1205 | Extra for Numbering and Certification (per basket) |
| 1206 | IQ/OQ/PQ Documentation Pack |
| 1209 | Electronic Temperature Calibration Key |
| 1228 | Qualification Tools |
| 1229 | Re-Calibration of Qualification Tools |
| 1307 | Printer (including USB cable) |

Electronic Temperature Calibration Key



Choose your DTGi System Accessories

Copley offers a complete range of accessories for use with the DTGi Series, from complete basket-rack assemblies to individual tubes, discs and sieve meshes.

All parts are manufactured to tolerances that are equal to or better than those quoted in the respective Pharmacopoeias. Certificates of Compliance can be supplied upon request.

DTGi Series Accessories

| Cat. No. | Description |
|----------|----------------------------------------------------|
| 1210 | Standard Basket Rack Assembly |
| 1205 | Extra for Numbering and Certification (per basket) |
| 1211 | Set of 6 Glass Tubes for Standard Basket |
| 1212 | Set of 6 Polycarbonate Discs for Standard Basket |
| 1213 | Set of 6 Sieve Meshes for Standard Basket |
| 1214 | 1000 mL Beaker |

Accessories for Specialist Dosage Forms

| Cat. No. | Description |
|----------|-----------------------------------------------------------|
| 1215 | Basket Rack Cover for Hard & Soft Gelatine Capsules |
| 1216 | Extra for Numbering and Certification (per cover) |
| 1217 | Special Basket Rack Assembly for Large Tablets & Capsules |
| 1218 | Extra for Numbering and Certification (per basket) |
| 1219 | Set of 3 Tubes for Special Basket |
| 1220 | Set of 3 Cylindrical Discs for Special Basket |
| 1221 | Sieve Mesh for Special Basket |

Hygiene: Anti-Bacterial/Algae Treatment

The addition of 1 mL of Aqua Stabil per month will prevent the build-up of bacteria and algae in the water bath, keeping the water clear, safe and odour-free.

| Cat. No. | Description |
|----------|------------------------------|
| 1372 | 100 mL Bottle of Aqua Stabil |

